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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,693	01/03/2002	Naoyuki Koizumi	2001-1930A	1850

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EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/07/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,693

Applicant(s)

Naoyuki et al

Examiner

SUDHAKER PATEL, D.Sc. Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 29, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 9
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Interview Summary

Application No.
10/019,693

Applicant(s)
Naoyuki et al

Examiner
SUDHAKER PATEL, D.Sc. Tech.

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All participants (applicant, applicant's representative, PTO personnel):

(1) SUDHAKER PATEL, D.Sc. Tech.

(3) _____

(2) Mr Jacob

(4) _____

Date of Interview Oct 3, 2003

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy is given to 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No. If yes, brief description:

Claim(s) discussed: Claims 18-26

Identification of prior art discussed:

None

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Applicants returned the call. Examiner informed them that upon further review and examination some issues related to 35 U.S.C. 112 para second, and homology of H vs -CH2-/-CH3 would have to be resolved by their clients. Office communication will be mailed for applicants' review with their overseas client.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

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DETAILED ACTION

Applicants' communication paper # 8 dated 9/29/03 is acknowledged.

Applicants have canceled claims 1-17 and presented new claims 18-26. Therefore, the claims in this application are the claims 18-26.

After further review and reconsideration, this application is found not ready for allowance at this stage for the reasons stated bellow.

Rejections withdrawn:

Rejections made under m 35 U.S.C. 112 paragraph second are now withdrawn because applicants have amended the claims now presented.

Rejections made under 35 U.S.C.112 paragraph one are now withdrawn because applicants have deleted the word "prophylaxis" in the claims.

New rejections (see interview summary):

Claim Rejections - 35 U.S.C. § 112

1.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 26 does not recite "in need thereof". Claim recites "administered to a human being". This language include any human being. Correction is required.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (U.S.P. 5192785, also cited as Chemical Abstract DN 119:249709).

Young teaches making of sulfamates with a core: "Phenyl-Phenyl-O-SO₂-NH₂".

Instant claims differ by not having instant X1 and X2 as H. However, the claim language also recite that one of them is a methyl (CH₃) which differs only by a --CH₂-- which is a homologue.

Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to prepare instant compounds by modifying or replacing as:

(I). Replacing H of -CH= of a phenyl ring by alkyl or methyl, and also

(II). Making the Me group attached at any one of the free positions of phenyl group/core as claimed herein, and try out the use/utility as a pharmaceutical by using

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the conventional chemistry knowledge. The motivation stems from the expectation of making compounds having equal or better medicinal agent.

Claims 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (EP 403185), also cited as Chemical Abstract DN 116:20788).

Young teaches making of sulfamates with a core: 'Phenyl-Phenyl-O-SO₂-NH₂'.

Instant claims differ by not having instant X1 and X2 as H. However, the claim language also recite that one of them is a methyl (CH₃) which differs only by a --CH₂-- which is a homologue.

Claims 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (U.S.P. 5025031, also cited as Chemical Abstract DN 115:255820).

Young teaches making of sulfamates with a core: 'Phenyl-Phenyl-O-SO₂-NH₂'.

Instant claims differ by not having instant X1 and X2 as H. However, the claim language also recite that one of them is a methyl (CH₃) which differs only by a --CH₂-- which is a homologue.

Note, the Phenyl group can be attached onto second phenyl group in different positions e.g. para-position to -O-SO₂-NH₂ i.e. 4-position or positions 2,3,5, or 6. This will provide positional isomers of the pthenyl core.

Analogous alkylene variations would be structurally obvious. See, In re Dillon, 919 F. 2d at 1904. See also Deuel, 51 F. 3d at 1558, 34 U.S.P.Q. 2d at 1214 ("Structural relationships may provide the requisite motivation or suggestion to modify

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one compound to obtain another compound(s)"). For example, one compound may suggest its homolog/isomer, because

homolog/isomer often have similar properties, and therefore, chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties, or merely to satisfy their production goals.

Claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F. 2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP 2141.02.

It has been held that a prior art disclosed compounds is sufficient to render a prima facie case of obviousness as species falling within a genus. See In re SUSI, 440 F 2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by Federal Circuit in Merck & co. V. Biocraft Laboratories, 847 F 2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir.1989). See In re Dillon 16 USPQ 2nd. 1897, 1923 regarding a prima facie case of obviousness of "structurally similar compounds disclosed by prior art" regardless to the properties disclosed in the inventor's application.

5. Claim 24 is objected to because of the following informalities: If claim 25 is allowed, this claim will be a duplicate of claim 25. Also, "agent" is not defined, and this will raise additional issues. Appropriate correction is required.

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Conclusion

Allowable Subject Matter

6. Claims 18-26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, objections made, and other rejections, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc. Tech., whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703)308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.


BRUCE KIFLE, PH.D.
PRIMARY EXAMINER

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October 3, 2003